

**REMARKS:**

Reconsideration of the rejections is respectfully requested.

The status of the claims is as follows:

<b>Amended:</b>	8, 18-19
<b>Cancelled:</b>	None
<b>New:</b>	None
<b>Pending:</b>	1, 3-19
<b>Allowed:</b>	1, 3-7, 13

The claims have been amended to more clearly define the invention. Support for the amendments is either apparent, or is as described in the text below. The recital of application to a surface of the substrate is supported in paragraph 0013 of the specification as published. The recital of a film is supported in paragraph 0016.

Applicant gratefully acknowledges the designation of claims 1, 3-7 and 13 as allowed.

**Claim Rejections - 35 U.S.C. §103(a)**

Claims 8-12 and 14-19 stand rejected under 35 U.S.C. §103(a), based on Yolles, US 4,344,431 and Sparks, US 4,940. This rejection is respectfully traversed.

There appears to be a fundamental disjunction between the applicant's reading of the claims and the examiner's, else the cited patents could not be deemed relevant by the Office. The claims recited (and still recite) that the thyroid hormone was in the product, and not simply in a process step, "substantially free of excipients." A polymer is an excipient.<sup>2</sup> Now while the claims recite that the drug is deposited on polymer (which could be an excipient, at least if in

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<sup>2</sup> The online Merriam-Webster dictionary defines "excipient" as "usually inert substance (as gum arabic or starch) that forms a vehicle (as for a drug)." Though this may or may not be the best reference from which to seek this definition, it is, Applicant respectfully submits, sufficient to confirm that one of skill would understand that polymers in admixture with drugs are excipients.

admixture), they nonetheless recite that the drug is substantially free of excipient. This can only mean, consistent with paragraph 0013 of the specification, that where the drug resides it is substantially free of excipient. This is because it is deposited on, not admixed with, the polymer. The revision to claim 8 seeks to make this clearer with recitations that were implied by the prior language (and which thereby do not change the scope of the claim).

With the above in mind, Yolles quite explicitly states at Col. 2, line 44, that the invention of this patent is very different:

It has now been unexpectedly found *that an intimate mixture* of a drug and a crystalline polymeric material can be formed to a solid, shaped article which will unexpectedly exude the drug to the surface of the polymeric article.

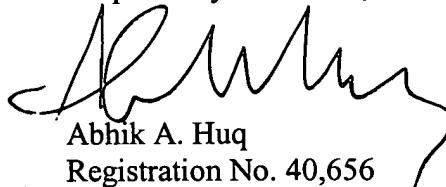
The examples in the Yolles patent relate to compositions formed from liquid admixture or from blending and extruding. These are indeed methods to obtain an intimate admixture – a concept fundamentally at odds with that of the present claims.

The particles of Sparks are "particles containing an active ingredient [and optionally an excipient] *in intimate admixture* with at least one non-toxic polymer." Col. 2, lines 64-66. Each of the particles "is in a form of a micromatrix with the active ingredient and the excipient, if present, *uniformly distributed throughout the polymer.*" Col. 2, line 66 – Col. 2, line 1. Thus, both Yolles and Sparks are fundamentally different from the claimed invention with respect to the same feature. Such intimate admixture as required in both Yolles and Sparks cannot come within the claims at issue. It cannot be obvious to drop a crucial feature of Yolles and Sparks. Accordingly, Applicant respectfully submits that the rejection is in error and should be withdrawn.

**Conclusion**

In light of these amendments and remarks, it is respectfully submitted that the Amendment should be entered, the rejections should be withdrawn, and that the application is in condition for allowance.<sup>3</sup>

Respectfully submitted,



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<sup>3</sup> **FEE DEFICIENCY**

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